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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,864	07/22/2003	Dietrich Wilhelm Schacht	25348	6414

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,864	SCHACHT ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response with traverse to the Restriction/Election requirements, provisionally electing invention I, and the self-adhesive matrix species as claimed in claim 6 (TDS system wherein the self-adhesive matrix comprises two or more silicone type pressure sensitive adhesives including a high-tack and a medium tack silicone-type adhesive (i.e. blend), each comprising a polysiloxane with a resin, is acknowledged and made of record.

The amendment of the claims is acknowledged and made of record.

The amendment of the Specification filed 3/7/07 to: a) provide cross-reference to a copending application having related subject matter, b) correct a typographical error by replacing "WO 94/07568" with "WO 94/07468" is acknowledged, c) delete paragraph bridging page 1 and 2 as it pertains to the discussion therein of a cited background reference (International Patent Publication No. WO 99/49852) to avoid any possibility of that discussion being potentially construed as mischaracterizing the disclosure of WO 99/49852 (Applicant asserts such wording was inadvertent and without deceptive intent and invites the Examiner to read WO 99/49852 to determine what is disclosed therein), and d) amend paragraphs on page 3 and bridging pages 9 and 10 to be in alignment with claim 1 as amended, is acknowledged. However, entry of said amendment is deferred to provide time for applicant to submit a separate paper to the Office with a statement that no new matter has been added by amendment.

Information Disclosure Statement

The information disclosure statement (IDS) filed 10/15/03 is acknowledged and made of record as it complies with the provisions of 37 CFR 1.97

Status of the Claims

Claims 1-7 are currently pending in this application and are the subject of the Office action.

Claim 7 is withdrawn for examination purposes for being directed towards non-elected subject matter.

Claims 1-6 are presented for examination.

Restriction/Election

Applicant's statement that the references in the Action at page 5 to the *"undue search burden that will be created by the multiplicity of tumor, viral and bacterial cells encompassed by these cells" and at page 6 to claims 1, 27, 28, 29, 30, 31, 38, 39, 42, 43, and 44" which are considered generic* are **inadvertently and erroneously presented therein**, and that the present response will be considered complete without addressing these further is acknowledged (see Applicant's Response filed 3/7/07, page 10, last paragraph). Said referenced portion, which was admittedly inadvertently and erroneously presented, is withdrawn. The Action mailed 12/7/06 is hereby amended to indicate that currently claims 1 and 2 are considered to be generic to the referenced species (see Action mailed 12/7/06, page 6, first full paragraph).

Applicant contends that 1) inventions 1 and II while being patentably distinct, are sufficiently closely related not to impose an undue search burden on the Examiner, and

2) a search for application to skin of a rotigotine-containing TDS to treat a rotigotine-treatable disease needs no more extensive databases than a search for the rotigotine-containing TDS itself.

3) individual species embraced by the generic claims, while being patentably distinct, are sufficiently closely related not to impose an undue search burden on the Examiner.

4) Claim 1 sets forth five characteristics of the self-adhesive matrix, which functionally define the transdermal delivery system (TDS); the particular species identified in the Office action represent embodiments of the TDS having these five characteristics.

Applicant's traversal arguments with respect to the restriction requirement (identified above as items 1 and 2) are not found to be persuasive for the reasons previously made of record in the Office action mailed 12/7/06. In addition, it is noted that a different search strategies would be required for invention I and invention II.

The election of species requirements are being withdrawn as applicant's traversal arguments are considered to be persuasive.

The restriction requirement is made final.

Objection

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computed tape used by the printer is limited. The form and legal phraseology

often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is need for consulting the full patent text for details. In the instant case, abstract is not in the form of a narrative. Applicant's cooperation is requested in correcting this deficiency in the abstract.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term *"optionally at least a crystallization inhibitor."* However, It is not clear what specific condition would require the *"optionally at least a crystallization inhibitor."* Thus, this term is found to be vague and indefinite.

Dependent claims 2-6 are rejected for the same reason as these claims fail to correct the deficiency of claim 1, from which they depend.

Claim 1 recites the term *"crystallization inhibitor."* However, the specification does not clearly define this term and reasonably leaves doubt as to the meaning of the invention to which the term refers, thereby rendering the definition of the subject-matter of said claims unclear. In this regard, although the specific examples are shown in the specification (e.g. polyvinylpyrrolidone, vinyl acetate, polyethyleneglycol, polypropyleneglycol, glycerol and fatty acid esters of glycerol or copolymers of

ethylene), the meaning of the instant claims should be clear from the claim language alone. Thus, the term *"crystallization inhibitor"* is deemed to be unclear.

Dependent claims 2-6 are rejected for the same reason as these claims fail to correct the deficiency of claim 1, from which they depend.

Claim 1 recites the term *"a multitude of microreservoirs."* This term is indefinite because it is not clear what this qualitative term specifically means.

Claim 2 recites the term *"the mean diameter of the microreservoir."* This term is indefinite because it lacks proper antecedent basis. It is suggested that this rejection may be overcome by amendment of the claim deleting the term *"the mean diameter of the microreservoir"* and replacing it with the term "a mean diameter of the microreservoir."

Claims 4-5 recite the term *"the polymer matrix."* This term is found to be indefinite for lacking proper antecedent basis. It is suggested that this rejection may be overcome by amending the claim to delete the term *"the polymer matrix"* and replacing it with the term "the self-adhesive matrix."

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected as being unpatentable over Mantelle et al. (US patent 6,316,022), in view of Brecht (US Patent Application Publication No. 2001/0053777), further in view of Rossi-Montero et al. (US Patent 6,465,004), further in view of Sackler (US Patent 5, 733,571), and further in view of Muller et al. (US Patent 6884434),

Mantelle et al. (US patent 6,316,022) teach a transdermal composition containing a **blend of one or more polymers (e.g. a blend of an acrylic based polymer and a silicone based polymer)**, one or more drugs (abstract; see also col. 3, line to col. 4, line 21). Mantelle et al. teach the silicone based polymers are broadly referred to as polysiloxane; suitable **polysiloxanes** include, **silicone pressure-sensitive adhesives**

which are based on two major components: a polymer, or elastomer, and a **tackifying resin** (abstract; see also col. 8, line 66 to col. 9, line 39; see also Table 1). Instant claim 4 recites the term *"wherein the polymer matrix comprises a silicone pressure sensitive adhesive,"* while instant claims 5 and 6 recite the term *"wherein the polymer matrix comprises two or more silicone pressure sensitive adhesives as the main adhesive components."* Mantelle et al. does not specifically teach that two or more silicone pressure sensitive adhesives; however, the use of two or more silicone pressure sensitive adhesives is reasonably construed to be within the knowledge and skill of an artisan skilled in the art in the absence of evidence to the contrary. Mantelle et al. disclose a transdermal composition which contains one or more drugs, and a **polymer matrix** comprising one or more high shear resistant polymers, wherein the high shear resistant polymer(s) reduce the plasticizing effect of a low molecular weight drug and exhibit **sufficient tack** and shear for application to a human being (abstract). Like Mantelle et al., claim 6 recites that the term *"adhesive comprise a high tack silicone pressure sensitive adhesive comprising polysiloxane with a resin"* (see col. 8, line 66 to col. 9, line 39). Unlike instant claim 6 which recites the language *"a blend of high tack silicone ... and a medium tack silicone pressure sensitive adhesive comprising polysiloxane ...,"* but Mantelle et al. does not teach a blend of high tack and medium tack silicone. However, the use of a blend of a high tack and medium tack silicone pressure sensitive adhesive is reasonable considered to be within the knowledge and skill of an artisan skilled in the art in view of the teaching of Mantelle et al., in the absence of evidence to the contrary (abstract). Mantelle et al. teach that the preferred

pressure-sensitive adhesive composition embodiment can be used as an adhesive portion of any TDS e.g. **a reservoir device**, or it can comprise an adhesive monolithic device; the principles of the invention still apply to embodiments where the TDS composition is not a pressure-sensitive adhesive and comprises a drug reservoir (col. 9, lines 56-62). Instant claim 1, recites the term *"which comprises a multitude of microreservoirs within the matrix."* For purposes of this rejection, the term *"which comprises a multitude of microreservoirs within the matrix"* given its broadest reasonable possible interpretation is construed to be a coextensive characteristic of the reservoir embodiment taught by Mantelle et al. (col. 9, lines 56-62). Mantelle et al. teach that **backing materials** are well known in the art and can comprise, for example, plastic films of polyethylene, vinyl acetate resins, polyester etc. (col. 10, lines 7-22); suitable release liners are also well known in the art (col. 10, lines 23-30). Instant claim 1 recites the term *"a backing layer."* Mantelle et al. teach a transdermal drug delivery system, a pressure-sensitive adhesive containing a medicament/drug, as a means for administering therapeutically effective amounts of the transdermal composition (col. 1, lines 29-51). Mantelle et al. teach a transdermal delivery system (TDS) that does not suffer from the loss of the drug, when present in the **free base form**, during manufacture of the TDS (col. 2, lines 22-49; see also reference claim 13). Instant claim 1 recites the term *"free base."* Mantelle et al. does not teach rotigotine, or a protective foil or sheet to be remove prior to use, or crystallization inhibitor, or an inert backing layer, however.

Brecht (US Patent Application Publication No. 2001/0053777) teach a method of treating restless leg syndrome comprising administering a therapeutic amount of an alpha2-agonist and a second agent such as a dopamine agonist e.g. rotigotine (also referred to as N-0923; see reference claim 12). Instant claims 1 recites the term *"rotigotine."* Brecht discloses that rotigotine is a preferred dopamine agonist (page 2, paragraph 0022). Breacht teaches that the combination of said active compounds (alpha-2 agonist + second agent) can be administered by oral, spinal, anal or intravenous route or by inhalation, subcutaneously or **transdermally** (paras. 0031-0034, 0037, and 0069). Brecht teaches that the active substance or combination of active substances are released either directly onto the outer layer of the skin using a transdermal plaster, in the form of a solution or gel e.g. embedded in a polymer matrix, through micro-pins or micro-cutters which penetrate the horny layer of the skin (para. 0033).

Rossi-Montero et al. (US Patent 6,465,004) teach composition and method for the continuous and controlled transdermal delivery of an active agent comprising a pharmaceutically active agent carrier and cellulose derivative, which provides a solubiling and stabiling effect on the active agents incorporated therein (abstract). Preferred cellulose derivatives include cellulose acetate butyrates (CAB); CABs are particularly suitable to suppress crystallization in pressure-sensitive adhesive carrier compositions containing steroid hormones (col. 5, lines 4-24). The use of soluble polyvinlypyrrolidone (PVP) as a drug **crystallization inhibitor** and solubility enhancer is

known in the art (col. 5, lines 24-26). Instant claim 1 recites the term *"optionally at least a crystallization inhibitor."*

Sackler (US Patent 5, 733,571) teaches that devices for administering drugs through the skin, wherein laminated composites include a delivery or reservoir layer containing a drug, a pressure sensitive adhesive layer for attaching the composite to the skin and a backing layer that forms the outer layer of the laminate; other systems incorporate the active agent into a matrix and/or an adhesive formulation which is deposited on an **inert backing layer** (col. 2, lines 46-59). Sackler teaches that the transdermal patch delivery system comprise a **substantially impermeable backing layer** (col. 3, lines 22-40). Instant claim 1, recites the limitation *"inert backing layer."*

Muller et al. (US Patent 6884434) teach a transdermal therapeutic system, comprising a **backing layer inert to the components of the matrix**, a self-adhesive matrix layer containing an active agent in an effective amount for the treatment of Parkinson's syndrome, and a **protective foil or sheet to be removed prior to use**, characterised by a matrix that is based on a non-aqueous, acrylate-based or silicone-based polymer adhesive system (abstract; see also col. 2, line 32 to col. 5, line 23). Instant claim 1 recites the term "*protective foil or sheet to be removed prior to use."*

The following terms recited in claim 1; namely, *"wherein the self-adhesive matrix comprises a solid or semi-solid semi-permeable polymer," "substantially impermeable to the protonated form of rotigotine," "and wherein the maximum diameter of the microreservoirs is less than the thickness of the matrix,"* are reasonably construed to be coextensive characteristics of the TTS self-adhesive matrix, absent evidence to the

contrary. The limitation recited in claim 2 *"wherein the mean diameter of the microreservoirs is in the range of 0.5 to 20 μm,"* and the limitation recited in claim 3 *"wherein the self-adhesive matrix is free of particles than can absorb salts of rotigotine at the TDS/skin interface,"* are reasonably construed to be pharmaceutical optimization which are within the skill and knowledge of an artisan skilled in the art, absent evidence to the contrary.

Based on the teaching of Mantelle et al., someone of skill in the art would have been motivated to combine the above discussed prior art teachings to create the instant inventive concept to take advantage of the reduced loss of free base drugs in the TTS during manufacture (col. 2, lines 22-49; see also reference claim 13).

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Relevant Art of Record

The following prior art references are made of record and relied upon are considered pertinent to applicant's invention.

Skluzacek et al. (US Patent 6,514,530) teach semipermeable polymers, including ethyl acrylate methylmethacrylate copolymers; acetaldehyde dimethylcellulose acetate; cellulose acetate ethylcarbamate; cellulose acetate methycarbamate; cellulose diacetate propylcarbamate; cellulose acetate diethylaminoacetate; semipermeable polyamide; semipermeable polyurethane; semipermeable sulfonated polystyrene; semipermeable crosslinked selective polymer formed by the coprecipitation of a

polyanion and polycation, semipermeable, lightly crosslinked polystyrenes; semi-permeable crosslinked poly(sodium styrene sulfonate); semipermeable crosslinked poly(vinylbenzyltrimethyl ammonium chloride) (col. 4, line 25 to col. 5, line 28).

Klein et al. (US Patent 6,899,894) teach transdermal therapeutic system in plaster form for controlled release of oestradiol in combination with norethisterone acetate, comprising a backing layer, a reservoir supersaturated with active ingredients which is attached to said backing and prepared using polyacrylate pressure sensitive adhesives and crystallization inhibitors, and a detachable protective layer, wherein the layer of thickness of the reservoir is from 0.02mm to 0.5 mm (abstract; see also col. 2, line 1 to col. 3, line 13). Klein et al. teach an adhesive solution is applied to the detachable protective layer of Hostaphan Rn 100, siliconized on both sides, to give after drying an active substance matrix, wherein a backing layer is impermeable to the active ingredients and is laminated onto the resultant matrix (col. 3, lines 7-13).

Klose et al. (US Patent 6,929,801) teach a transdermal delivery of anti-Parkinson's agents wherein rotigotine is disclosed (col. 3, lines 11-29; see also reference claims 1 and 9).

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double (ODP) patenting as being unpatentable over claims 5-16 of copending US Patent Application No. 10/429,283 (Appl. '283), in view of Brecht (US Patent Application Publication No. 2001/0053777). It is noted that claims 5-16 are considered to be in pending status as these claims have not been cancelled of record. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, reference claim 1 is directed towards a transdermal therapeutic system (TTS) comprising a self-adhesive matrix layer containing (-)-5,6,7,8-tetrahydro-6-[propyl [2-(2-thienyl)ethyl]amino]-1-naphtol, a backing that is inert to the components of the matrix, and a protective film that is to be removed prior to use.

Brecht (US Patent Application Publication No. 2001/0053777) teaches a method of treating restless leg syndrome comprising administering a therapeutic amount of an alpha2-agonist and a second agent such as a dopamine agonist e.g. rotigotine (also referred to as N-0923; see reference claim 12).

Thus, instant claims 1-6 are deemed obvious variants of the limitations of claims 5-16 of Appl. '283 in view of Brecht.

Claims 1-6 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending US Patent Application No. 10/627,990 (Appl. '990) claims 1-13, in view of Brecht. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

The discussion of Brecht in connection with the above ODP rejection is incorporated by reference.

In particular, reference claim 1 is directed towards a transdermal delivery system (TDS) comprising a backing layer, a self-adhesive matrix containing an amine functional

drug; and a protective foil or sheet to be removed prior to use, wherein the self-adhesive matrix comprises a solid or semisolid semi-permeable polymer.

Thus, instant claims 1-6 are deemed obvious variants of the limitations of claims 1-13 of Appl. '990 in view of Brecht.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Claim rejections – 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall

set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals which are crystallization inhibitors, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-6 are directed to encompass non-disclosed crystallization inhibitors

which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these non-disclosed crystallization inhibitors meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the specifically disclosed crystallization inhibitors, the skilled artisan cannot envision the detailed chemical structure of the non-disclosed crystallization inhibitors encompassed by the instant claims, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the chemically structurally defined crystallization inhibitors, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3 August 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER